A phase III, single-arm study to evaluate the efficacy and safety of ONCOFID-P-B (paclitaxel-hyaluronic acid conjugate) administered intravesically to patients with BCG- unresponsive Carcinoma in Situ of the bladder with or without Ta-T1 papillary disease

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- persistent or recurrent confirmed carcinoma in situ (CIS) of the bladder - unresponsive to BCG treatment and refuse radical cystectomy or are not clinically suitable for cystectomy - able to walk and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours - women and men of child bearing age must follow specific requirements for birth control

Exclusion Criteria:

- current or previous muscle-invasive cancer or metastatic urothelial cancer - current or prior systemic therapy for bladder cancer. - women who are pregnant or breast feeding - additional medical or mental health diagnosis (study staff will review)

Conditions & Interventions

Interventions:
Drug: ONCOFID P-B (PACLITAXEL-HYALURONIC ACID)
Conditions:
Cancer
Keywords:
Clinics and Surgery Center (CSC), Bladder Cancer in Situ (CIS), Bladder CIS

More Information

Description: The purpose of this study is to understand if the study medication ONCOFID-P-B is effective and safe in treating patients with carcinoma in situ of the bladder who have not received benefit from standard BCG treatment and are not candidates for radical cystectomy.
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Phase: PHASE3
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